

REMARKS

This application is a continuation of issued parent U.S. Patent No. 6,613,039, titled Safety Guide for Surgical Placement of Sharp Instruments, issued September 2, 2003. This continuation application claims the benefit of the October 29, 2003 filing date of said prior related application.

In response to Office Action of September 9th, 2009, Applicants acknowledge entry of Claims 9-26 by Applicant's Petition to Revive Application from Unintentional Abandonment and Response to Office Action filed April 3rd, 2009. The Examiner objected to Applicants' prior Response to Office Action as non-responsive to prior art cited in previous Non-Final Office Action of July 9th, 2007.

Upon entry of this Response and Amendment the previously entered Claims 9-26 are cancelled and new Claims 27-51 are pending in the present application. New Claims 27-33 are amended versions of originally examined Claims 1-7 responsive to the Non-Final Office Action of July 9th, 2007. Appendix 1 is included with mark-ups to original Claims 1-7 for the Examiner's convenience. Claims 34-51 are new claims. The foregoing Amendments do not add new matter to the present application. Applicants hereby respectfully request reexamination and reconsideration of the application.

In the first Non-Final Office Action of July 7th, 2007, original Claims 1-6 and 8 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Original Claims 1-3 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Villegas* (U.S. Patent No. 2,581,564). Original Claims 1-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Fukuda* (U.S. Patent No. 4,345,604).

1. Response to Rejection of Claims 1-6 and 8 (see Original Claims 1-6 and 8, Appendix 1)

Under 35 U.S.C. § 112, Second Paragraph:

In the Non-Final Office Action of July 9, 2007, Original Claims 1-6 and 8 were rejected under 35 U.S.C. § 112 as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

New Claim 27 (corresponding to Original Claim 1, Appendix 1) explicitly points out and distinctly claims the subject matter the Applicants regard as the invention. More specifically, Claim 27 distinctly recites a recess in the second end of the sharp instrument. The indexing means (reference numeral 21 in Figure 4) referred to by the Examiner is inferentially claimed for the purpose of clarity and is not part of the claimed invention. The indexing means is located on the holder mechanism of the safety guide

BLACK LOWE & GRAHAM PLLC

25315

CUSTOMER NUMBER

-9-

SDEV-1-1003ROA

701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

(reference numeral 3) and is received by the recess.

Claims 28-31 are allowable because they depend from independent Claim 27, which is allowable.

Claim 32 explicitly points out and distinctly claims a selectively lockable safety sheath that includes an annular locking vane. No such locking vane is shown, taught, or suggested by the art of record. New Claim 32 is allowable because it depends from independent Claim 27, which is allowable.

2. Response to Rejection of Claims 1-3 (see Original Claims 1-3, Appendix 1) Under 35 U.S.C. § 102(b) in view of Villegas (U.S. Patent Serial No. 2,581,564):

In the Non-Final Office Action, original Claims 1-3 (see Appendix 1) were rejected under 35 U.S.C. § 102(b) as being unpatentable in view of *Villegas* (U.S. Patent Serial No. 2,581,564). Applicants respectfully traverse the rejection above for at least the following reasons.

New independent Claim 27 (corresponding to Original Claim 1, Appendix 1) is allowable for at least the reason that *Villegas* does not disclose, teach, or suggest the feature of “a selectively lockable safety sheath,” *Villegas* does not disclose, teach, or suggest using a safety sheath for receiving a sharp end of an elongate rod. Accordingly, *Villegas* does not anticipate Claim 27, and the rejection should be withdrawn. Furthermore, the cited references fail to show, teach, or suggest any comparable structure.

Claims 28 and 29 are allowable because they depend from independent Claim 27, which is allowable, and because they include additional patentable features. These features include a rod “bent such that the second end defines a second portion and a second longitudinal axis non-colinear with respect to the first longitudinal axis” and a recess with “a linear axis in a plane defined by the longitudinal axes.”

3. Response to Rejection of Claims 1-8 (see Original Claims 1-8, Appendix 1) Under 35 U.S.C. § 102(b) in view of Fukuda (U.S. Patent Serial No. 4,345,601):

In the Non-Final Office Action, Claims 1-6 and 8 (corresponding to Original Claims 1-6 and 8, Appendix 1) were rejected as lacking novelty under 35 U.S.C. § 102(b) in view of *Fukuda* (U.S. Patent Serial No. 4,345,601). Applicant traverses the rejection of Claims 1-6 and 8 for at least the following reasons.

New independent Claim 27 (corresponding to Original Claim 1, Appendix 1) is allowable for at least the reason that *Fukuda* does not disclose, teach, or suggest using an elongate rod defining a *longitudinal axis*. *Fukuda* discloses “an arcuately curved suturing needle” (Column 3, lines 27-28). Accordingly, *Fukuda* does not anticipate Claim 27 and teaches away from the claimed invention.

25315

CUSTOMER NUMBER

-10-

SDEV-1-1003ROA

BLACK LOWE & GRAHAM PLLC

701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

Claims 28-32 are allowable because they depend from independent Claim 27, which is allowable, and because they include additional patentable features including a rod “bent such that the second end defines a second portion and a second longitudinal axis non-colinear with respect to the first longitudinal axis” (Claim 28); a recess with “a linear axis in a plane defined by the longitudinal axes” (Claim 29); a sheath locked onto the elongate rod “wherein the sheath is sufficiently elongated so as to substantially cover the sharp point” (Claim 30); a locking device “configured to selectively grip a shaft of the sharp instrument, holding the sharp pointed end within” (Claim 31); and the selectively lockable safety sheath further including “an annular locking vane defining a circular aperture adapted to receive the first end of the sharp instrument in a first unlocked position and movable to a second locked position” (Claim 32).

New independent Claim 33 is allowable for at least the reason that *Fukuda* does not disclose, teach, or suggest using a *linear* guide beam. *Fukuda* discloses that “[t]he needle cap 13 has entered the flanged end 16 ... after completing a *circular* arc with the suturing needle 11.” (Column 4, lines 4-7). Accordingly, *Fukuda* does not anticipate and in fact teaches away from the subject matter of dependent Claim 33.

4. Newly Added Claims 34-51:

New Claims 34-51 are based on subject matter that is explicit and/or inherent within the description of the specification and/or the drawings.

New dependent Claims 34-36 and 39-40 are directed toward features of the receiver mechanism of a safety guide, including: “an end face defining an open bore-hole ... a receiver standard fixed to one end of the guide beam ... a receiver pin that intersects the receiver and the receiver standard ... a releasable safety sheath having an elongated cylindrical body defining a diameter substantially the same as the bore-hole” configured to receive the releasably insertable safety sheath (Claim 34); “a sheath-retaining pawl” configured “so that the safety sheath is selectively removable from the receiver bore-hole” (Claim 35); a receiver standard with “a protruding ridge vane for activating the pawl” configured to release “the safety sheath from the receiver bore-hole” (Claim 36); a key “having a wedge-shaped tip and oriented substantially perpendicular to the longitudinal axis of the interior cavity” to relieve “the interference between the locking vane and the received sharp instrument whereby the sharp instrument can be removed from the safety sheath” (Claim 39); and a key and a thumb press bar configured to engage the key ... enabling removal of the received sharp instrument from the receiver” (Claim 40).

New dependent Claims 37-38 are directed toward features of the safety sheath of the receiver

25315

CUSTOMER NUMBER

mechanism including: a safety sheath with “a target at an end face of the cylindrical body facing the holder mechanism and defines a round hole substantially the same diameter as a shaft of the sharp instrument and configured to receive the instrument point” (Claim 37) and “a positionable locking vane, a compressible sheath spring, and opposing first and second faces of the interior cavity” to engage “the sharp instrument preventing the removal of the sharp instrument from the safety sheath” (Claim 38).

New dependent Claims 41-45 are directed toward features of a holder mechanism and a guide beam of the safety guide including: . the guide beam with “a boot selectively supported by the guide beam and a crickle configured to be reversibly straightened by actuation of the thumb press bar ... preventing removal of the sharp instrument from the receiver mechanism when the safety guide is re-closed” (Claim 41); the holder has “a groove positioned longitudinal to a second longitudinal axis of the sharp instrument, at least one pair of holder element levers ... and a reset lever” configured to hold or release a shaft of the sharp instrument (Claim 42); the holder with “a ram and a ram support guide” (Claim 43); a safety guide “wherein the first end of the safety guide, the second end of the safety guide, and the guide beam are configured to cooperatively guide the point of the sharp instrument into the receiver, placing the sharp instrument safely through the skin of a patient (Claim 44); and a safety guide is configured in which the safety sheath at a first end is “permanently fixed to the point of the sharp instrument after one placement of the instrument through a patient’s skin” (Claim 45).

New independent Claims 46, 50 and 51 and dependent Claims 47-49 are directed towards methods of using the safety device. Specifically, Claims 46-47 are directed toward a method for preventing more than a single use of a sharp instrument without a reset of an accompanying safety guide, including the steps of “preventing the holder and receiver from being slid away from one another along the guide beam until a reset action of the safety guide is performed” (Claim 46); and “releasing the sharp instrument from the holder of the safety guide; actuating the sheath-retaining pawl, enabling the sheath to be separated from the receiver; and actuating the reset lever, enabling the holder and receiver to be slid apart from one another” (Claim 47).

New dependent Claims 48-49 are directed to a method for one-handedly separating a safety sheath from a safety guide, including the steps of “rotating the receiver about the receiver pin, causing the protruding ridge vane of the receiver standard to interfere with the sheath-retaining pawl, leading the sheath-retaining pawl to retract from the notch in the sheath; actuating the reset lever of the safety guide; and pulling the boot of the safety guide from the slot in the guide beam” (Claim 48); and “rotating the receiver about the receiver pin, causing the protruding ridge vane of the receiver standard to interfere

BLACK LOWE & GRAHAM PLA

25315

CUSTOMER NUMBER

-12-

SDEV-1-1003ROA

701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

with the sheath-retaining pawl, leading the sheath-retaining pawl to retract from the notch in the sheath; actuating the reset lever of the safety guide; and pulling the boot of the safety guide from the slot in the guide beam” (Claim 49).

New independent Claim 50 is directed to a method for maintaining control of a point of a sharp instrument using an accompanying safety guide, including the steps of “disabling the key whenever the sharp instrument is outside a holder of a safety guide; providing a release lever configured to release the sharp instrument from the holder; and disabling the release lever whenever the point of the sharp instrument is outside the safety sheath.”

New independent Claim 51 is directed to a method of using a sharp instrument and safety guide for operating on a patient including the steps of “releasably inserting a sharp instrument sheathed in a safety sheath into a receiver of a safety guide; releasably securing a shaft of the sharp instrument in a holder mechanism releasing the sharp instrument from the safety sheath; sliding the holder mechanism, including the secured sharp instrument, along a guide beam away from the receiver mechanism of the safety guide; positioning the safety guide so that the holder mechanism securing the sharp instrument and the receiver mechanism are on opposite sides of the patient’s skin; sliding the holder mechanism, including the secured sharp instrument, along the guide beam toward the receiver mechanism, passing the sharp instrument through the patient’s skin; receiving a tip of the sharp instrument in the safety sheath; releasing the shaft of the sharp instrument from the holder mechanism of the safety guide; and releasing the safety sheath, including the sheathed instrument, from the receiver mechanism of the safety guide.”

No new matter has been added in the new Claims 34-51 and that new Claims 34-51 are believed to be allowable over the cited prior art. Therefore, Applicants respectfully request the Examiner to enter and allow the above new claims.

25315

CUSTOMER NUMBER

-13-

SDEV-1-1003ROA

BLACK LOWE & GRAHAM PLLC

701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending Claims 27-51 are believed to be in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at 206-957-2464.

Respectfully submitted,

/Wendy M. Gombert/

By: Wendy M. Gombert, PhD.
Reg. No. 61,968
Black, Lowe & Graham PLLC
701 Fifth Avenue, Stc. 4800
Seattle, WA 98104
Telephone: 206.381.3300
Facsimile: 206.381.3301

25315

CUSTOMER NUMBER

-14-

SDEV-1-1003ROA

BLACK LOWE & GRAHAM PLLC

701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

APPENDIX 1

25315

CUSTOMER NUMBER

-15-

SDEV-1-1003ROA

BLACK LOWE & GRAHAM



701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

ORIGINAL CLAIMS AS FILED MARKED TO SHOW CHANGES IN NEW CLAIMS 27-33.

1. A surgical trochar sharp instrument and sheath, comprising:
an elongate rod having first and second ends, the first end having a sharp point and an upper portion defining a first longitudinal axis a sharp pointed end (first end), and [[a]] the second end with having means to connect for connecting a tube thereto, [[and]] wherein [[said]] the second end also has includes a recess configured to receive an indexing means of a safety guide for rotationally orienting the elongate rod with respect to the first longitudinal axis; and
a selectively and longitudinally lockable safety sheath for receiving the first end of the rod.
2. The surgical trochar sharp instrument of Claim [[1]]27, wherein [[said]] the rod is bent such that [[said]] the first end is at an angle to said second end defines a second portion and a second longitudinal axis non-colinear with respect to the first longitudinal axis.
3. The surgical trochar sharp instrument of Claim [[2]]28, wherein [[said]] the recess has a linear axis in the plane of said bend defined by the longitudinal axes.
4. The surgical trochar sharp instrument and sheath of Claim [[1]]27, wherein [[a]] the sheath is locked onto the first end of the elongate rod, thereby covering and wherein the sheath is sufficiently elongated so as to cover the [[said]] sharp point.
5. (Currently Amended) The surgical trochar sharp instrument and sheath of Claim [[4]]27, wherein [[said]] the sheath has a locking means to fasten device configured to selectively grip a shaft of the sharp instrument, holding the sharp pointed end within.
6. (Currently Amended) The surgical trochar sheath of Claim [[4]]30, wherein [[said]] the selectively lockable safety sheath includes an annular locking vane defining a circular aperture adapted to receive the first end of the sharp instrument in a first unlocked position and movable to a second locked position.

25315

CUSTOMER NUMBER

7. (Currently Amended) A sharp instrument and a safety guide for installing a surgical trochar (sharp instrument) placing the sharp instrument through the skin of a patient, comprising:

a sharp instrument;

a first end of a safety guide having a receiver mechanism adapted for lockably accepting a safe trochar a sharp point of the sharp instrument; and

a second end of a safety guide having a holder mechanism adapted for releasable securing said safe trochar (sharp instrument) the sharp instrument in all directions; and

a guide beam having a linear elongated body and a substantially uniform cross-section along its length, wherein said the receiver mechanism and said the holder mechanism are guided in continuous linear alignment along at least a portion of the guide beam such that the sharp end point of said safe trochar (sharp instrument) the sharp instrument will follow follows a substantially straight line from within the receiver mechanism to a point separate position apart from the receiver mechanism and back again into the receiver mechanism when the safety guide is actuated.

8. (Cancelled)

25315

CUSTOMER NUMBER

-17-

SDEV-1-1003ROA

BLACK LOWE & GRAHAM PLLC

701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301